Sheet 1

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Coi	nplete if Known	
Application Number	10/748,096	_
Filing Date	December 30, 2003	
First Named Inventor	Doddabele L. Madhavi	
Art Unit	1623	
Examiner Name	Matthew L. Fedowitz	
Attorney Docket Number	BIO 2-013	

Examiner	Cite	Document Number	Publication Date	DOCUMENTS  Name of Patentee or	Pages, Columns, Lines, Where
Initials*	Cite No.1	Number-Kind Code <sup>2 (f known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		Number-Kind Code			
M-	ŀ	<sup>US-</sup> 2003/0012774A1	01-16-2003	Moldenhauer, et al.	-
¥		<sup>US-</sup> 6,461,593	10-08-2002	Hanioka, et al.	
		US-DE10139851	03-13 2003	Waltraud, et al.	+
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		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>3</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	י
		EP1174109	01-23-2003	Nielsen, et al.		
		JP56109590	08-31-1981	Yonezawa, et al		
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INFO	te for form 1449/PTO		-	Complete if Known				
Supstitu	10 101 101111 1773/ 10			Application Number	10/748,096			
INFO	ORMATION	DIS	CLOSURE	Filing Date	December 30, 2003			
STA	TEMENT B	Y A	PPLICANT	First Named Inventor	Doddabele L. Madhavi			
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Sheet	2	of	4	Attorney Docket Number	BIO 2-013			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	"Accumulation and retention of micellar b-carotene and lutein by Caco-2 human intestinal cells", J. Nutr. Biochem., 10: 573-581, 1999.	
	2.	"Inclusion complexation of CoQ-10 with cyclodextrins", Acta Pol. Pharm., 52:379-386, 1995	
	3.	"Investigation of inclusion complexes of CoQ-10 with g-cyclodextrin and methyl-b-cyclodextrin. Part I. Comparison of complexation methods in the solution state", Acta Pol. Pharm., 53: 193-196, 1996a.	
	4.	"Investigation of inclusion complexes of CoQ-10 with g-cyclodextrin and methyl-b-cyclodextrin. Part II. The influence of complexation temperature (heating method) on CoQ-10 solubility", Acta Pol. Pharm., 53: 197-201, 1996b.complexation temperature (heating method) on CoQ-10 solubility", Acta Pol. Pharm., 53: 197-201, 1996b.	
	5.	"Investigation of inclusion complexes of CoQ-10 with g-cyclodextrin and methyl-b-cyclodextrin. Part III. The influence of cyclodextrins on CoQ-10 stability", Acta Pol. Pharm., 54: 279-285, 1997	
	6.	"A moderate interaction of maltosyl-alpha-cyclodextrin with Caco2 cells in comparison with the parent cyclodextrin", Biol. Pharm. Bull., 24: 395-402, 2001.	
	7.	"Uptake and passage of beta lactoglobulin, palmitic acid and retinal across the Caco-2 monolayer", Biochim. Biophys. Acta., 1236: 149-154, 1995.	
	8.	"Cyclodexrins as mucosal absorption promoters of insulin. II. Effects of beta-cyclodextrin derivatives on alpha-chymotryptic degradation and enteral absorption of insulin in rats". Pharm Res. 11: 1174-9, 1994.	
	9.	"Intestinal safety of water soluble beta-cyclodextrins in pediatric oral solutions of spironolactone: effects on human epithelial Caco-2 cells", J. Pharm. Pharmacel. 49: 43-8, 1997.	
	10	"Vitamin E uptake by human intestinal cells during lipolysis in vitro", Gastroenterology, 98: 96-103, 1990.	

Examiner	11/1	Date	adalas
Signature	- Forth	Considered	40105
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Substitu	te tor form 1448/PTO			Application Number	10/748,096
INFO	DRMATION	DIS	CLOSURE	Filing Date	December 30, 2003
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Doddabele L. Madhavi
				Art Unit	1623
	(Use as many she	ets as r	necessary)	Examiner Name	Matthew L. Fedowitz
Sheet	3	of	4	Attorney Docket Number	BIO 2-013

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	11	"Transepithelial transport of putrescine across monolayers of the human intestinal epithelial cell line, Caco2", World J. Gastroenterol., 7: 193-197, 2001.	
	12	"Improvement of dissolution and absorption characteristics of ubidecarenone by dimethyl-b-cyclodextrin complexation", Acta Pharm. Nord., 1: 99-104, 1989.	
	13	"The effect of parenterally administered cyclodextrins on cholesterol levels in the rat", Pharm. Res., 8: 9-16, 1991	
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M	16	"Comparison of impact of the different hydrophilic carriers on the properties of piperazine-containing drug", Eur. J. Pharm. Biopharm., 51: 221-225, 2001.	
	17	"Gemparative study on inclusion complexation of maltosyl-beta-cyclodextrin, heptakis(2,6-di-O-methyl)-beta-cyclodextrin and beta-cyclodextrin with fucosterol in aqueous and solid state", J. Pharmacol., 45: 1028-32, 1993	
ME	18	"Effect of inclusion complexation with cyclodextrins on photostability of nifedipine in solid state", Int. J. Pharm., 243: 107-17, 2002	
M	19	"Enhancement of dissolution and oral bioavailabilty of gliquidone with hydroxypropyl-beta-cyclodextrin", Pharmacia, 2003: 58 (11): 807-10	
M	· 20	Physiocochemcial characterization and in vitro dissolution behavior of nicardipine hydrochloride inclusion compounds". Eur J Pharm Sci. 2002 Feb; 15(1): 79-88	

Examiner Signature	Date Considered	9/30/05
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Subetit	de for form 1449/PTO				Complete if Known
·	NFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use as many sheets as necessary)	Application Number	10/748,096		
INF	ORMATION	DIS	CLOSURE	Filing Date	December 30, 2003
STA	ATEMENT E	BY A	PPLICANT	First Named Inventor	Doddabele L. Madhavi
				Art Unit	1623
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Sheet	4	of	4	Attorney Docket Number	Bio 2-013

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ME	21	Effect of the hydrophobic nature of triacetyl-b-cyclodextrin on the complexation with nicardipine hydrochloride: physicochemical and dissolution properties of the kneaded and spray-dried complex*, Chem Pharm Bull (Tokyo). 2002 Dec; 50 (12): 1597-602	
1	22	"Preparation and characterization of albendazole beta-cyclodexrin complexes", Drug Dev Ind Pharm. 1999 Dec; 25(12) :12418	
	23	"Influence of the preparation method on the physicochemical properties of ketoprofen-cyclodextrin binary systems", Int J Pharm. 1999 Mar 1; 179(1): 117-28	
	24	"Influence of the preparation method on the physicochemical properties of binary systems of econazole with cyclodextrins", Int J Pharm. 1999 Dec 20; 193(1): 85-95	
V	25	"Review-Cyclodextrins in topical drug formulations: Theory and Practice", Int. J. Pharm, 225: 15-30, 2001	

Examiner Signature	Date Considered	9/30/03

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